FROM-AKERMAN SENTERFITT FEB--15-06 01:19PM

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T-884 P.10/14 F-030

In re Application of: SNYDER, R.O. et al.

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REMARKS

Applicants are filing herewith a Request for Continued Examination (RCE) due to the finality of the Office Action.

Applicants have amended claims 1, 20, and 29. No new matter has been added by virtue of these amendments and their entry is respectfully requested.

Claim Rejections Under 35 U.S.C. § 112

Claims 1-19 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement.

The Examiner asserts that the scope of the amended claims is broader than the instant disclosure in that the claims read on a nucleic acid molecule comprising at least one adenoviral helper functions in reverse orientation to the first and second AAV sequences. Applicants respectfully traverse.

However, in order to compact prosecution and expedite allowance of the application, Applicants have amended the claims as per the Examiner's suggestions. This is not to be construed as acquiescence or surrender of subject matter. Applicants hereby, reserve the right to file one or more Continuation or Divisional applications claiming said subject matter.

In view thereof, Applicants respectfully request reconsideration and withdrawal of the instant rejection.

Claim Rejections Under 35 U.S.C. § 102

Claims 20-32 are rejected under 35 U.S.C. § 102(e) as being anticipated by Gao et al.

Applicants respectfully traverse.

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Applicants have amended claims 20-28 by including the subject matter of claim 1 in claim 20 wherein claims 21-28 include the subject matter of independent claim 20. As amended, claim 20 (and dependent claims therefrom), recites sequences in the nucleic acid molecule which are neither taught or disclosed by Gao et al.

In view thereof, Applicants respectfully request reconsideration and withdrawal of the instant rejection.

Claims 20-27 and 29-33 are rejected under 35 U.S.C. § 102(a) and (e) as being anticipated by Fraites et al.

Applicants respectfully traverse.

Applicants have amended the claims to recite the generation of the cap proteins using the primers of SEQ ID NO's: 1-4 in an amplification reaction. That is, Applicants teach a nucleic acid molecule comprising a first nucleotide sequence encoding an AAV Rep protein of a first serotype; a second nucleotide sequence encoding an AAV Cap protein of a second serotype generated by SEQ ID NO's.: 1-4; the second serotype being different from the first serotype; and, a third nucleotide sequence, encoding a transcription product having an Adenoviral VA helper function, in reverse orientation to said first and second nucleotide sequences.

Furthermore, Applicants teach that plasmids pXYZ1 and pXYZ5 were used to pseudotype AAV2-ITR-containing expression cassettes into AAV1 and AAV5 capsids respectively. See, for example, page 17, lines 24-26.

Fraites et al., do not teach or disclose a cell comprising a nucleic acid molecule said nucleic acid molecule comprising: a first nucleotide sequence encoding an AAV Rep protein of a first serotype; a second nucleotide sequence encoding an AAV Cap protein of a second serotype generated by amplifying SEQ ID NO's.: 1-4; the second serotype being different from the first serotype; and, a third nucleotide sequence encoding a transcription product containing an

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adenoviral sequence encoding a VA Adenoviral helper function. Thus, Fraites do not teach each

and every claim limitation.

In view thereof, reconsideration and withdrawal of the rejection are requested.

Accordingly, Applicants submit that the rejection no longer applies to claims 20-27 and 29-23,

and respectfully request reconsideration and withdrawal of the rejection.

Claim Rejections Under 35 U.S.C. § 103

Claims 33-36 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Gao et al.,

in view of Rabinowitz et al.

Applicants respectfully traverse. Gao et al has been discussed above and for the sake of

brevity will not be repeated here. Gao et al does not teach or disclose the instant invention.

Rabinowitz et al does not teach or disclose a method of producing rAAV virions, the

method comprising the steps of: (a) culturing a cell comprising a nucleic acid molecule

comprising: a first nucleotide sequence encoding an AAV Rep protein of a first serotype; a

second nucleotide sequence encoding an AAV Cap protein of a second serotype; the second

serotype being different from the first serotype; and, a third nucleotide sequence encoding a

transcription product containing an adenoviral sequence encoding a VA Adenoviral helper function whereby, rAAV virions are produced; and, (b) isolating the rAAV virions produced

from the cell wherein a second nucleotide sequence encoding an AAV Cap protein of a second

serotype generated by amplifying SEQ ID NO's.: 1-4; the second serotype being different

from the first serotype wherein the step (b) of isolating the rAAV virions produced from the cell

comprises subjecting the produced rAAV virions to an iodixanol step gradient.

Neither reference, alone or in combination teaches or suggests the claimed limitations, for

example first, second, third nucleic acid molecules, SEQ ID NO's: 1-4. Furthermore, neither

reference provides or suggest or motivates one of ordinary skill in the art to combine these

references and arrive at the instant claimed invention.

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In view thereof, Applicants respectfully request reconsideration and withdrawal of the instant rejection.

Claim Rejections under 35 U.S.C. § 112, second paragraph

Claims 1-19 were rejected under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regards as his invention.

Applicants have amended claim 1 to indicate that the AAV cap protein is generated when using primers SEQ ID NO's: 1-4 in an amplification reaction.

In view thereof, Applicants respectfully request reconsideration and withdrawal of the instant rejection.

CONCLUSION

In view of the foregoing, reconsideration and withdrawal of all rejections and allowance of the application with claims 1-36 are respectfully solicited. The amended claims set forth, herein, are merely to expedite prosecution and allowance of the application and is not to be construed as surrender of any subject matter in the instant application. Applicants hereby reserve the right to pursue the subject matter of the canceled claims in one or more continuations, continuation-in-part or divisional patent applications.

If there are any remaining issues or the Examiner believes that a telephone conversation with the Applicants' attorney would be helpful in expediting prosecution of this application, the Examiner is invited to call the undersigned at telephone number shown below.

Although, Applicants believe that no extensions of time are required with submission of this paper, Applicants request that this submission also be considered as a petition for any extension of time if necessary. The Commissioner for Patents and Trademarks is hereby

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authorized to charge the amount due for any retroactive extensions of time and any deficiency in any fees due with the filing of this paper or credit any overpayment in any fees paid on the filing or during prosecution of this application to Deposit Account No. 50-0951.

Respectfully submitted,

AKERMAN SENTERFITT

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Docket No. 5853-258-1CON

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